K071350

510(k) Summary

AUG 2 2 2007

Company Name: Cardiovascular Systems, Inc.
651 Campus Drive
St. Paul, MN 55112

Contact: Michael Kallok PhD, FACC, Chief Scientific Officer

Phone: (651) 259-1610

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Summary Date: May 9, 2007

Trade Name: Diamondback 360° Orbital Atherectomy System

Common Name: Peripheral Atherectomy Device

Classification Name: 21 CFR 870.4875, Peripheral Atherectomy Catheter

Predicate Device:

510(k) Number: K901206
Manufacture: Heart Technologies (Acquired by Boston Scientific)
Trade Name: Rotablator Peripheral Atherectomy Device

510(k) Number: K043553
Manufacture: Fox Hollow, Inc.
Trade Name: Silver Hawk Peripheral Plaque Excision System

510(k) Number: K041630
Manufacture: Cardiovascular Systems, Inc.
Trade Name: CSI A-V Graft System

1.0 Description of Device

The Diamondback 360° Orbital System (OAS) is intended for use in the treatment of peripheral artery stenosis also referred to as Peripheral Artery Disease (PAD). PAD is the result of a stenosis of peripheral arteries, typically in the legs.

The OAS provides a method of removing stenotic material from peripheral arteries. The OAS applies a diamond coated, eccentrically rotating cutting surface to ablate stenotic material. The resulting particles of removed stenotic material are very small and can be absorbed by the body.

The technology of applying a rotating abrasive surface to remove a peripheral stenotic material has a technology predicate. The Cardiovascular Systems, Inc. (CSI) rotational atherectomy system, commercial name CSI A-V Graft System, was reviewed and cleared to market for use in A-V Grafts by 510(k) K041630. This same device, with modifications to the indication for use and additions of disposable device variations is applied for use in atherectomy of peripheral arteries.

The Diamondback 360° Orbital Atherectomy System consists of the following three significant components:

1) Orbital Atherectomy Device,
2) Guide Wire, and
3) Controller.

2.0 Intended Use

The Diamondback 360° Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries are who are acceptable candidates for percutaneous transluminal atherectomy.

3.0 Technology

The Diamondback 360° Orbital Atherectomy System (OAS) provides a method of removing occlusive neointimal tissue. The OAS applies a diamond coated, eccentrically rotating cutting surface to ablate neointimal tissue. The resulting particles of removed neointimal tissue are very small and can be absorbed by the body. This same technology was cleared to market for use in A-V Grafts, reference K041630.

4.0 Conclusions

The OAS is substantially equivalent to the predicate devices. Laboratory animal and clinical data were provided to support the safety of the Diamondback 360° Orbital Atherectomy System. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2007

Cardiovascular Systems, Inc.
c/o Michael J. Kallok, Ph.D.
Chief Scientific Officer
651 Campus Drive
St. Paul, MN 55112-3495

Re: K071350
Diamondback 360°™ Orbital Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II (Two)
Product Code: MCW
Dated: July 27, 2007
Received: July 30, 2007

Dear Dr. Kallok:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071350

Device Name: Diamondback 360° Orbital Atherectomy System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lechner

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K071350